DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 4 2004

C.R. Bard, Incorporated
C/O Ms. Michaela Rivkowich
Senior Regulatory Affairs Specialist
Bard Access System, Incorporated
5425 West Amelia Earhart Drive
Salt Lake City, Utah 84116

Re: K033389
Trade/Device Name: PowerPICC™ Catheters, Models 3175155& 3175135
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: January 12, 2004
Received: January 13, 2004

Dear Ms. Rivkowich:

This letter corrects our substantially equivalent letter of January 12, 2004 regarding the trade name and the regulation name.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent [(for the indications for use stated in the enclosure)] to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

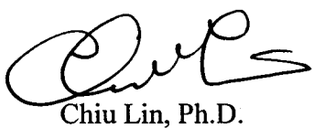
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 1.2

5 Fr Single Lumen PowerPICC™ Catheter
Abbreviated 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Senior Regulatory Affairs Specialist of Bard Access Systems, that this notification [510(k)] for the following devices, **5 Fr Single Lumen PowerPICC** catheters, is indicated for the following:

> The **PowerPICC** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the **PowerPICC** catheter may not exceed 300 psi.

Signature of 510(k) Submitter: Michaela Rivkowich

Typed Name: Michaela Rivkowich
Senior Regulatory Affairs Specialist

Date: 1/12/04

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

✓ Prescription

Concurrence of Office of Device Evaluation

510(k) Number K033389

Division Sign-Off Office of Device Evaluation: Anne Norcross (Interim Branch Chief) 3/18/04

JMN
(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K033389

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K033389

Section 7

510(k) Summary of Safety and Effectiveness Information

PowerPICC™ Catheter

7.1 Submitter Information

Submitter Name:	Bard Access Systems, Inc. (BAS) [Subsidiary of C. R. Bard, Inc.]
Address:	5425 W. Amelia Earhart Drive Salt Lake City, UT 84116
Telephone Number:	(801) 595-0700, Ext. 5541
Fax Number:	(801) 595-4903
Contact Person:	Michaela Rivkowich
Date of Preparation:	January 12, 2004

7.2 Device Name

Device Name:	PowerPICC™ Catheter
Trade Name:	PowerPICC™ Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital

7.3 Predicate Device(s):

Device Name:	Poly Per-Q-Cath® PICC Catheter
Trade Name:	Poly Per-Q-Cath®PICC Catheter
Common/Usual Name:	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Class II, 80 LJS – Long Term Intravascular Catheter
Classification Panel:	General Hospital
Premarket Notification:	K031129, concurrence date May 5, 2003

7.4 Device Description

- The **PowerPICC** Catheters are open-ended radiopaque polyurethane catheters.
- Catheter size is 5 Fr SL with 50 cm usable length.
- The catheter has a reverse taper design.
- Catheter shaft tubing is marked with depth indicators, with "0" indicated to serve as a reference for the catheter insertion point.
- Catheters are provided sterile in basic radiology PICC configurations.
- Purple colorants were added to the catheter materials to provide the catheter with an appearance that allows the end user to differentiate the **PowerPICC** from other PICC catheters.
- The catheter extension leg, junction and clamp ID tag were printed with markings to identify the catheter as **PowerPICC** and to include information to facilitate proper use of the device.

7.5 Intended Use

The **PowerPICC** catheters are intended for short-term or long-term peripheral access to the central venous system for intravenous therapy and blood sampling.

This is the identical intended use for the predicate Poly Per-Q-Cath® PICC.

7.6 Indications for Use

The **PowerPICC** catheter is indicated for short or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media. For blood sampling, infusion or therapy, use a 4 French or larger catheter. The maximum recommended infusion rate is 5cc/sec. The maximum pressure of power injectors used with the **PowerPICC** catheter may not exceed 300 psi.

7.7 Technological Characteristics Summary

New device is compared to Marketed Device

Yes.

Does the new device have the same indication statement?

The indications for use were expanded to include power injection of contrast media and to provide more detail for blood therapy.

Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?

No, the differences do not alter the intended use of the device.

Does the new device have the same technological characteristics, e.g. design, material, etc.?

Not in all regards. The **PowerPICC** has some minor differences from the predicate Poly Per-Q-Cath® PICC. However, the basic fundamental scientific technology of the catheter has not changed.

Could the new characteristics affect safety or effectiveness?

Yes. The new characteristics could affect safety or effectiveness of the device.

Do the new characteristics raise new types of safety and effectiveness questions?

No. There are no new types of safety and effectiveness questions.

Do accepted scientific methods exist for assessing effects of the new characteristics?

Yes. The FDA's *Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters*, dated 3/16/95, and relevant ISO 10555 Standards were used to determine the appropriate methods for evaluating the modified device's performance.

Biocompatibility requirements of ISO-10993, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, and the FDA-Modified ISO 10993 Test Profile for externally communicating, blood-contacting, long-term devices, will be met.

Are performance data available to assess effects of new characteristics?

Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards.